PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P5048PC00	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IS 03/00023	International filing date *(day/month/year)* 12.08.2003	Priority date *(day/month/year)* 12.08.2002
International Patent Classification (IPC) or both national classification and IPC A61K31/727		
Applicant SVEINSSON, Birkir		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11.03.2004	09.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Beeck, M Telephone No. +49 89 2399-8473

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IS 03/00023

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-20	as originally filed

Claims, Numbers

10-14	as originally filed
1-9	received on 22.11.2004 with letter of 22.11.2004

Drawings, Sheets

1/6-6/6	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-5

   because:

   ☒ the said international application, or the said claims Nos. 1-5 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-8,12-14
	No:	Claims	9-11
Inventive step (IS)	Yes:	Claims	1-8,12-14
	No:	Claims	9-11
Industrial applicability (IA)	Yes:	Claims	6-14
	No:	Claims	

2. Citations and explanations

see separate sheet

D1: NOVOTNY, FRANTISEK: "Psoriasis Treatment by heparin" ACTA UNIVERSITATIS CAROLINAE MEDICA, vol. 31, no. 3/4, 1985, pages 243-245, XP002274846

D2: US-B-6 214 8161 (POLIVKA ZDEN EACUTE K ET AL) 10 April 2001 (2001-04-10)

SECTION III:

Claims 1 to 5 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

SECTION V:

1) Document D2 already describes pharmaceutical compositions comprising a CGRP antagonist (see the abstract, column 1, line 24, and the claims).

Therefore the subject-matter of claim 9 to 11 is not novel (Article 33 (2) PCT).

2) The use of CGRP antagonists for the treatment of psoriasis is not obvious in view of the documents cited in the Search report.

Therefore the subject-matter of claims 1 to 8 and 12 to 14 involves an inventive step.

3) For the assessment of the present claims 1 to 5 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

10/524104
WO 2004/014351 PCT/IS2003/000073
DT01 Rec'd PCT/PTO 10 FEB 2005

Unchanged

CLAIMS

1. A method of treating, remedying or preventing psoriasis in a subject comprising administering to the subject a therapeutically effective dose of at least one CGRP antagonist compound in a pharmaceutically acceptable formulation.

2. The method according to claim 1, wherein the at least one CGRP antagonist compound is selected from the group consisting of 4-sulfinyl benzamide compounds, 3,4-dinitrobenzamide compounds, benzamidazolinyl piperadine compounds, anti-CGRP antibodies, CGRP derivatives including the peptide CGRP 8-37, tryptase active polypeptide, and the compound BIBN4096BS, ~~and compund stabilising tryptase, including heparin~~.

dl.

3. The method according to claim 1, wherein the CGRP antagonist compound is administered locally , such as topically, dermally, intradermally, or subcutaneously, or via dermal or subcutaneous infusion such as through microdialysis administration.

4. The method according to claim 1, wherein the CGRP antagonist compound is administered orally, nasally, rectally, pulmonary, buccally or via subcutaneous, intravenous or intramuscular injection.

5. The method according to claim 1, wherein the CGRP antagonist compound is administered topically.

6. The use of a CGRP antagonist compound for the manufacture of a medicament for treating, preventing or remedying psoriasis in a subject.

7. The use according to claim 6, wherein the compound is selected from the group comprising 4-sulfinyl benzamide compounds, 3,4-dinitrobenzamide compounds, benzamidazolinyl piperadine compounds, anti-CGRP antibodies, CGRP derivatives including CGRP 8-37, tryptase, ~~tryptase-stabilizing compounds including heparin~~, and the compound BIBN4096BS.

dl.

8. The use according to claim 6, wherein the medicament is administered topically.

9. A pharmaceutical composition for treatment of psoriasis comprising at least one active CGRP antagonist substance and at least one pharmaceutically acceptable excipient.